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No. 01-847

In the Supreme Court of the United States

APOTEX USA, INC.,
Petitioner,

v.

MERCK & CO., INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Respondent Merck & Co., Inc. discovered and began using a formulation process to make a very successful high blood pressure medication, known as VASOTEC®. Merck has used its process since at least 1983 and has sold VASOTEC® since 1986. After Merck disclosed its manufacturing process to Apotex Canada in open court during Canadian patent litigation in 1994, Petitioner Apotex USA prosecuted and obtained two U.S. patents to cover Merck's process, and then sued Merck for allegedly infringing those patents.

Not surprisingly, the district court granted summary judgment that Merck was the prior inventor of the claimed processes and invalidated Apotex USA's patents under 35 U.S.C. § 102(g), which prevents patents being obtained on inventions previously made by another who had not abandoned, suppressed, or concealed such invention. The Federal Circuit affirmed, holding that Merck's testimony in open court and its other public disclosures provided clear and convincing evidence that Merck made knowledge of its earlier invention of the accused process available to the public and had not suppressed or concealed it. Based on the above, the only question presented by this case is:

Whether the Court of Appeals correctly affirmed the district court's summary judgment that the Petitioner's patents were invalid under 35 U.S.C. § 102(g), where Merck discovered, used, and disclosed the patented process years before Petitioner's named inventor even "conceived" of his alleged invention days after Merck's process was disclosed in open court and where Petitioner's remaining arguments distort the statutory language, mischaracterize the lower court and foreign court proceedings, and advance new arguments not supported by the statute or the record?

RULE 29.6 STATEMENT

No parent or publicly held company owns 10% or more of Respondent, Merck & Co., Inc.'s, stock.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

Respondent Merck & Co., Inc. ("Merck") respectfully urges this Court to deny the petition for writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit. Having lost on summary judgment, on rehearing, on appeal (unanimously), and again on rehearing, the petitioner, Apotex USA, Inc. ("Petitioner" or "Apotex USA"), has not presented a single valid basis upon which this Court should grant certiorari. Instead, Apotex USA concocts "important questions of Federal law" and attributes its loss to outlandish claims of fraud by Merck and of incredulous ineptitude by both the Court of Appeals and the District Court. However, the lower courts correctly held that the undisputed evidence in this particular case clearly demonstrated that Merck's accused process had been invented by Merck long before Apotex USA tried to patent it, so that Apotex USA's asserted patents were invalid as a matter of law under 35 U.S.C. § 102(g).

OPINIONS BELOW

The Federal Circuit's decision for which Petitioner seeks review by this Court is *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031 (Fed. Cir. 2001). Pet. App. A, 1a-17a. The Federal Circuit's order denying Petitioner's petition for panel rehearing and rehearing en banc is reproduced at Pet. App. D, 46a. The opinions of the district court on summary judgment, Pet. App. B, 18a-38a, and denying reconsideration, Pet. App. C, 39a-45a, are not officially reported, but can be found at *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000) and *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 656670 (N.D. Ill. Mar. 17, 2000), respectively.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1338(a). The Federal Circuit, whose jurisdiction was based on 28 U.S.C. § 1295(a)(1), entered the judgment of which Apotex seeks review in its petition on June 8, 2001. Pet. App. A, 1a. The Federal Circuit denied rehearing on August 2, 2001. Pet. App. D at 46a-47a. Apotex invokes the jurisdiction of this Court under 28 U.S.C. § 1254(1).

The petition for certiorari was filed on October 31, 2001 and docketed on December 6, 2001. Upon Merck's request, this Court extended Merck's deadline for filing a response until January 22, 2002.

CONSTITUTIONAL AND STATUTORY POSITIONS INVOLVED

35 U.S.C. § 102(g) is the only constitutional or statutory provision that the Court would need to consider to resolve this case. As explained herein, Apotex USA's

arguments fall into three categories: 1) disagreement with fact finding and proper application of legal principles to those facts; 2) an attempt to manufacture an issue of first impression by baselessly attempting (in direct contradiction to federal statute and Federal Circuit precedent) to read a requirement into 35 U.S.C. § 102(g) that a person challenging the validity of a patent on the basis of section 102(g) prior art must prove that the United States public was aware of such art following a suppression or concealment; and 3) a claim that Merck did not satisfy, in the context of a summary judgment motion, 35 U.S.C. § 282, despite the fact that a) Apotex USA did not raise this issue below,[1] thereby waiving it, and b) the provision of section 282 in question only applies in the context of trial.

STATEMENT OF THE CASE

I. Procedural History

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc. ("Merck Frosst"), filed a Canadian lawsuit against Apotex USA's Canadian affiliate, Apotex, Inc. ("Apotex Canada"). Apotex Canada was infringing a Canadian patent owned by Merck Frosst that covered an active ingredient in an anti-hypertension medication known as "enalapril maleate." Merck has made hypertension medication utilizing the active ingredient, enalapril maleate, under the name, VASOTEC®, since 1983. In 1994, during the course of the Canadian litigation, Merck played, in open

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[1] Apotex USA first attempted to raise an issue about Merck's compliance with section 282, after changing lead counsel, in a motion for leave to file supplemental authority in support of its petition for a rehearing. The Federal Circuit properly denied Apotex USA's motion and rejected Apotex USA's supplemental brief, *sua sponte*, presumably because it raised new issues not presented previously.

court, a silent videotape of one of its employees demonstrating Merck's process for formulating VASOTEC® tablets. Brian McLeod, Merck Frosst's Vice-President of marketing at the time narrated the tape and explained Merck's formulation process.[2] Dr. Bernard Sherman, President of Apotex Canada, at the time, attended at least portions of the Canadian trial.

After Merck disclosed its formulation process in detail, Dr. Sherman filed applications for U.S. patent Nos. 5,573,780 ("the '780 patent") and 5,690,962 ("the '962 patent") (collectively "the Apotex USA patents"), which he assigned to Apotex USA. When the Apotex USA patents issued, Apotex USA brought the present case against Merck in the United States District Court for the Northern District of Illinois for Merck's alleged infringement of the Apotex USA patents.

Merck filed a motion for summary judgment of invalidity under 35 U.S.C. § 102(f) based upon Merck's contention that Dr. Sherman derived the invention claimed in the Apotex USA patents from Merck by filing the applications for the Apotex USA patents based upon information that he learned about Merck's process for formulating VASOTEC® tablets from Merck in the Canadian litigation. Pet. App. B, 29a-30a. The district court denied that motion on the basis of issues of material fact, because Dr. Sherman claimed that he did not attend trial on the particular day when Merck disclosed its formulation process in open court to Apotex Canada's litigation team and anyone

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[2] *See* transcript of March 28, 1994 of Brian McLeod trial testimony in *Merck & Co., Inc. et al. v. Apotex, Inc.* in the Federal Court of Canada ("McLeod Canadian Tr. Tran."), Trial Division, which is of record and can be found at A251-A257 in the Joint Appendix before the Federal Circuit in this case.

else who was present in the courtroom and that he did not learn the details of Merck's public disclosure later. *See* Pet. App. B, 30a; Joint Appendix to Federal Circuit Appeal, A77-A97.

Later, the parties filed cross motions on the issue of infringement, and Merck filed a motion for summary judgment of invalidity of the two Apotex USA patents under 35 U.S.C. § 102(g). The district court granted Apotex USA's motion for summary judgment of infringement and Merck's motion for summary judgment of invalidity, and denied Merck's motion for summary judgment of noninfringement. Pet. App. B, 18a-38a. The basis of Merck's section 102(g) motion was that, to the extent that Merck's process infringed the Apotex USA patents, that process was invalidating prior art to the Apotex USA patents because the Merck process predated Apotex USA's alleged conception of the process claimed in the Apotex USA patents by many years. Apotex USA filed a motion for reconsideration of the district court's summary judgment, which the district court denied. Pet. App. C, 39a-45a.

Apotex USA appealed the district court's summary judgment of invalidity of both Apotex USA patents under section 102(g) to the Federal Circuit, and the Federal Circuit affirmed the decision of the district court. Pet. App. A, 1a-17a. Apotex USA sought a panel rehearing and a rehearing en banc, which the Federal Circuit denied. Pet. App. D, 46a. The Federal Circuit also denied *sua sponte* a motion by Apotex USA seeking leave to file supplemental authority.

II. Merck's Disclosures Proved that No Abandonment, Suppression or Concealment Was Possible as of the Time of Dr. Sherman's Alleged Conception

Merck published the ingredients used in manufacturing its VASOTEC® tablets at least as early as the release of its 1992 VASOTEC® Product Monograph (the "Product Monograph"), Pet. App. A, 3a, which was publicly available since October 1992, and throughout 1993 and 1994. Pet. App. A, 3a, 16a; *see also* Pet. App. B, 35a. More than 30,000 copies of the Product Monograph were distributed in 1993 alone. Pet. App. A, 3a; Pet. App. B, 35a. Dr. Sherman even admitted that he had learned of Merck's ingredients from the Product Monograph. Pet. App. A, 16a-17a. Moreover, Merck had also published the ingredients used in manufacturing its RENITEC® enalapril tablets (i.e., the trademark used for VASOTEC® tablets sold in certain foreign countries) as early as the 1988 edition of the *Dictionnaire Vidal*, a French pharmaceutical reference publication.[3] Pet. App. A, 3a, 16a.

The steps of Merck's process were the subject of public testimony at the 1994 trial in the Canadian litigation. On March 28, 1994, Mr. Brian McLeod, then Vice-President of Marketing for Merck Frosst, presented a tutorial in open court and disclosed Merck's process for manufacturing VASOTEC® tablets. Pet. App. A, 3a, 16a; Pet. App. B, 20a, 25a-26a, 35a-36a. The specific ingredients used in the process were already published in the Product Monograph.

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[3] The *Dictionnaire Vidal* disclosure, which like the Product Monograph disclosed the ingredients of Merck's VASOTEC® tablets, will not be referred to separately in the remainder of this Brief as all statements made about the Product Monograph also apply to the *Dictionnaire Vidal*.

With the assistance of a videotape shown in open court during his testimony, Mr. McLeod provided a verbal and visual, step-by-step explanation of Merck's process. Not only was Mr. McLeod's testimony presented directly to Apotex Canada's agents (i.e., Apotex Canada's attorneys) in the courtroom that day, but it was also available to Dr. Sherman (Apotex Canada's president in 1994), Apotex Canada's other employees and experts, the rest of the pharmaceutical industry and to the general public because neither the testimony nor the videotape was subject to any protective order or confidentiality restrictions. Pet. App. A, 3a-4a; Pet. App. B, 35a.

It was not and could not be disputed that:

- As early as October 19, 1992, the Product Monograph publicly disclosed that "[i]n addition to the active ingredient, enalapril maleate, each tablet contains non-medicinal ingredients including iron oxides, lactose, magnesium stearate, sodium bicarbonate and starch." Product Monograph attached in Joint Appendix to Federal Circuit Appeal, A165; Pet. App. B, 26a.

- On March 28, 1994, Mr. McLeod publicly testified:

  - Disclosing Merck's process for manufacturing VASOTEC® tablets. He described the "steps that [Merck] follow[s] in taking the active ingredient from enalapril maleate into a final dosage form." *See* McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1006, lines 10-14; *see also* Pet. App. A, 3a, 16a; Pet. App. B. 25a-26a, 35a.

- That the ingredients of VASOTEC®, other than the lubricant (magnesium stearate), are mixed in a planetary mixer. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1007, lines 10-25, A1010, lines 15-20. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1007-A1010.

- That water is added to the mixture of the ingredients to create a damp mass in a wet granulation step. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, lines 2-13; *see also* Pet. App. B, 25a. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, lines 12-13.

- That the damp mass is dried by spreading it on trays and baking it in a drying oven. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, line 24 - A1010, line 8; see also Pet. App. B, 25a-26a. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, line 24 – A1010, line 8.

- That the dried ingredients are ultimately tableted (after they are blended with the

> lubricant – magnesium stearate). McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1010, lines 15-20; *see also* Pet. App. B, 26a. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal at A1010, line 10-A1011, line 7.

- Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of Dictionaire Vidal. Pet. App. A, 3a, 16a.

Dr. Sherman admitted that, given Merck's disclosure of the ingredients (specifically enalapril maleate and sodium bicarbonate) and their mixing in a wet granulation process with water, the occurrence of the acid-base reaction was obvious. Dr. Sherman made this admission in a statement that he prepared in connection with the 1994 trial in the Canadian litigation setting out the evidence that he intended to introduce with respect to his understanding of Merck's process. The courts below recognized this admission. Pet. App. C, 41a-42a; Pet. App. A, 16a-17a. In particular, Dr. Sherman stated that:

> Since enalapril maleate has acidic functional groups, it is obvious to any knowledgeable [sic] formulator or chemist that, when enalapril maleate and sodium bicarbonate are mixed and wetted [in a wet granulation], there will be an acid-base reaction. Dr. Sherman's VASOTEC Tablets Statement of Facts attached in Joint Appendix to Fed. Cir. at A1096 at ¶ 7.

Thus, Apotex USA's own chairman and named inventor has admitted that Merck's disclosure informed anyone knowledgeable in this field, which includes anyone at Apotex Canada, of Merck's formulation process to make VASOTEC® tablets. Apotex USA Admissions attached in Joint Appendix to Fed. Cir. at A1096 at ¶ 21. The courts below so concluded. Pet. App. B, 37a; Pet. App. A, 16a-17a.

The indisputable facts could not have made this case any clearer. Merck directly disclosed its process to Apotex USA and to Dr. Sherman, who then sought and received the patents to Merck's process. Apotex USA has argued and reargued its theory that Merck's disclosure was not proper. The petition for certiorari presents no compelling reasons for its grant, and is nothing more than a desperate attempt to avoid the finality of the Federal Circuit's decision.

REASONS FOR DENYING THE PETITION

This is a case in which Merck scientists were the undisputed first inventors of the accused process. Merck discovered the process and has practiced it since 1983. In the context of a Canadian litigation, Merck presented its process to Dr. Sherman and the Canadian affiliate of Apotex USA in 1994 without any confidentiality restrictions. Shortly after this disclosure and having lost the Canadian litigation, Dr. Sherman applied for the now invalidated patents, assigned them to Apotex USA, and, on the day of their issuance, sued Merck for practicing its own method.

The courts below examined the undisputed facts, including the opinion by the Canadian court, and concluded that, at the very least, as of the time that Dr. Sherman made his alleged invention, Merck was not suppressing or concealing its prior art process. Since this predated the earliest possible conception date by Dr. Sherman, the courts

ruled that Apotex USA was not entitled to valid patents that would cover Merck's process.

Thus, Merck presented an undisputed and clear-cut case of first inventorship. And, simply put, the courts below properly concluded that no reasonable person could decide that Merck was concealing its previously discovered process while at the same time it was openly disclosing it to its competitor, Dr. Sherman.

"Review on a writ of certiorari is not a matter of right, but of judicial discretion. A petition for a writ of certiorari will be granted only for compelling reasons." Sup. Ct. R. 10. The petition falls far short of providing compelling reasons for granting a writ. The petition: fails to raise any issue of first impression, argues an issue waived at previous stages in the case, relies upon an inapplicable statute, and simply takes issue with the particular result that the United States District Court for the Northern District of Illinois reached in a particular case and the Federal Circuit's decisions to affirm the district court decision. This brief addresses Apotex USA's arguments in the order in which Apotex USA presents them in its petition.

I. The Petition Does Not Raise A Question Of Special Importance With Regard To "Multi-National Drug Companies' Participation In The Patent Systems Of Different Countries."

Apotex USA has raised nothing more in its petition than a disagreement with: the district court's conclusion that no genuine issues of material fact existed; the district court's application of the law to the facts; the district court's reconsideration of its decision; and the Federal Circuit's decisions, on two occasions, to uphold the decision of the district court. While Apotex USA takes great issue with each

of these decisions, they are nevertheless decisions on a particular issue, concerning a particular patent and particular prior art and are based upon a record containing all of the relevant evidence. Apotex USA's attempt to wave global, current events before the Court does not transform an adverse decision on a summary judgment motion into an issue of international importance, much less an issue justifying a grant of certiorari by this Court.

Merck has disputed vehemently and continues to dispute Apotex USA's contention that Merck's position in the present litigation is in any way contrary to the position Merck took in previous litigation in Canada. Both the district court and the Federal Circuit have agreed with Merck. But even if, for argument's sake, Merck's present position were contrary to its position in the previous Canadian litigation (which it is not), Apotex USA has made no showing that such an inconsistency should implicate this Court's powers to grant certiorari. *See* section III.A., *infra*.

II. The Petition Does Not Present Any Important Questions Of Federal Law Yet Undecided By This Court, But, Rather, Presents Flawed Arguments Based On Misstatements Of Fact And Law.

A. Merck Did Not Need to Prove That the Evidence Negating Suppression and Concealment Was Known to People in the United States

Apotex USA attempts to conjure up an issue of first impression for this Court by misconstruing section 102(g) of the patent statute and the decisions of the district court and Federal Circuit. In pertinent part, section 102(g) provides that: "[a] person shall be entitled to a patent unless – ... (2) before such person's invention thereof, the invention was

made in this country by another inventor who had not abandoned, suppressed, or concealed it." The case law has held that a previous invention that was abandoned, suppressed, or concealed will, nevertheless, constitute invalidating prior art if the abandonment, suppression or concealment is negated before the second inventor "invents" the patented invention. *See* Pet. App. 15a-16a; *Paulik v. Rizkalla*, 760 F.2d 1270, 1275 (Fed. Cir. 1985).

Contrary to Apotex USA's argument, neither section 102(g) nor the case law places any requirement whatsoever on one challenging a patent based upon section 102(g) prior art to prove by clear and convincing evidence that anyone in the United States had actual knowledge of the acts negating suppression or concealment. The case law has succinctly set out that publication is not a prerequisite for the lack of suppression or concealment. *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401-03 (Fed. Cir. 1997). For example, the Federal Circuit stated in *Oddzon* that the lack of suppression or concealment is not synonymous with an affirmative duty to make a prior invention public:

> [S]ubsection (g) relates to prior inventions of others that are either public **or** will likely become public in the sense that they have not been abandoned, suppressed, or concealed.

Id. at 1402 (emphasis added). The *Oddzon* opinion in discussing the 1984 amendments to 35 U.S.C. section 103 again reaffirmed that "an earlier invention which is not public may be treated under Section 102(g) ... as prior art." *Id.* at 1403 (citing Section-by-Section Analysis: Patent Law Amendments Act of 1984, 130 Cong. Rec. 28069, 28071 (Oct. 1, 1984), *reprinted in* 1984 U.S.C.C.A.N. 5827, 5833. That the second inventor need not have access to a prior invention and that it does not even need to be "known in the

art" was also expressly set out in *Du Pont v. Phillips Petroleum Co.*, 849 F.2d 1430 (Fed. Cir. 1988), where the Federal Circuit specifically sanctioned the "secret nature" of section 102(g) prior art:

> [T]he requirement of proving no abandonment, suppression or concealment does mollify somewhat the "secret" nature of § 102(g) prior art.

Id. at 1437. Therefore, Apotex USA's contention that Merck had to prove that any disclosure it made reached the public is contrary to the law.

In granting summary judgment that Apotex USA's patents were invalid based upon Merck's previous invention, the district court explained:

> By its plain language, the statute [(section 102(g))] requires only that the [prior art] process is invented in the United States, not that the process be employed or disclosed in the United States after being invented. *See also Paulik v. Rizkalla*, 760 F.2d 1270, 1278 (Fed. Cir. 1985)(Rich, J., concurring). Judge Rich, who was intimately involved in drafting § 102(g), explained that one of the earlier versions of the statute required more of the inventor's activities to occur in the United States; specifically, it required that the prior invention be "made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice...." *Paulik*, 760 F.2d at 1278 (Rich, J., concurring). ***That language was taken out in favor of the current version,***

> ***which requires only that the invention be made in this country and not abandoned, suppressed or concealed in any country.*** *Id.* The undisputed record evidence shows that Merck's scientists invented the accused process and reduced it to practice at Merck's lab in West Point, Pennsylvania.

Pet. App. B, 31a (emphasis added). This statement of the law was well reasoned and soundly based upon both the history of the statute and the case law interpreting it.

In its decision on Apotex USA's motion for reconsideration, the district court further explained:

> [a]t the hearing on Apotex's motion to reconsider, Merck argued that § 102(g) does not require disclosure of the invention to the public; it simply requires that the invention is neither concealed nor suppressed. The Court quite agrees and tried to make this point clear in its January 20 opinion. *See Apotex Corp.*, 2000 U.S. Dist. LEXIS 641, No. 96 C 7375, 2000 WL 97582, at *8. *See also E.I. DuPont*, 849 F.2d at 1437 ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment.") Thus, whether Merck made its invention "known to the art" or publicly known is immaterial as long as Merck did not otherwise suppress or conceal its invention. As explained above and in the Court's earlier opinion, it did not.

Pet. App. C, 45a](noting that Apotex USA's own exhibits demonstrated that at least one member of the public was

present in court when Merck's expert described Merck's process). Thus, the Court explained not only that Apotex USA's argument was contrary to Federal Circuit precedent, but that, even under the rule urged by Apotex USA, Merck would have satisfied the rule.

The Federal Circuit agreed that acts negating suppression or concealment need not occur within the United States:

> As an initial matter, we disagree with Apotex's interpretation of § 102(g) as requiring proof negating suppression or concealment to arise from activities occurring within the United States. The plain language of § 102(g) clearly requires that the prior invention be made "in this country." However, in light of the grammatical structure of § 102(g), it would be a strained reading of that provision to interpret the language "in this country" to also modify the requirement that the prior invention was "not ...abandoned, suppressed, or concealed." A more reasonable interpretation is that it only modifies the antecedent verb "made," but not the "abandoned, suppressed, or concealed" clause that follows it. Had Congress intended the phrase "in this country" to modify "abandoned, suppressed, or concealed," it would have inserted language to that effect.
>
> Indeed, if there were any doubt, the legislative history of § 102(g) demonstrates that Congress contemplated that precise

> modification, as it applied to another clause in § 102(g), and failed to adopt it.

Pet. App. A, 7a-8a. If the negating act need not have occurred in the United States, then where would the legal basis be for requiring Merck to show that someone in the U.S. had knowledge of negating acts abroad? The answer is that no such basis exists, and Apotex USA's argument is plainly contradicted by the language of the statute, its legislative history, and the case law. In fact, the patent statute provides for a number of other types of invalidating prior art, such as foreign patents and publications, which require no proof that anyone in the United States was aware of the art. *See* 35 U.S.C. §§102(a), (b). The bottom line is that Apotex USA attempts to create an issue of first impression by urging the Court to read an additional requirement into section 102(g) that does not exist and is in fact precluded by existing legal authority. The Federal Circuit appropriately affirmed summary judgment on the basis of Merck's disclosures abroad and Apotex USA's own admissions concerning the public availability of information about Merck's invention. Pet. App. A, 16a-17a.

B. Apotex USA's Argument Concerning Section 282 Is Inappropriate

1. Apotex USA Has Waived Any Argument It Could Have Made Concerning Merck's Compliance With Section 282

Apotex USA never raised an issue concerning Merck's compliance with 35 U.S.C. § 282 at the district court level – either in its opposition to Merck's motion for summary judgment or in its motion for reconsideration of the district court's decision on summary judgment. Likewise,

Apotex USA did not raise such an argument in its brief on appeal to the Federal Circuit or in its Combined Petition for Panel Rehearing and Rehearing En Banc. In fact, it was only after changing lead counsel, that Apotex USA attempted to raise an issue under section 282 for the first time at the Federal Circuit in its Motion for Leave to File Supplemental Authority in Further Support of Rehearing. The Federal Circuit denied that motion *sua sponte*, as inappropriate. Apotex USA cannot for the first time raise new arguments in its attempt to relitigate this case for the fifth time.

2. Even if Apotex USA's Argument Were Timely, it Does Not Raise an Important Question of Federal Law, Misses the Issue, and is Simply Disagreement with the District Court's Factual Findings and Legal Conclusions in a Particular Instance

Apotex USA's argument is case specific – Apotex USA argues that Merck's identification of its own prior invention and use of the very process that Apotex USA accused of infringement was inadequate ***in this particular case*** to satisfy a statute designed to give an opponent thirty days' notice of evidence in advance of a trial. The Petition blatantly misstates the law at page 6, when it describes pretrial disclosure under section 282 as a requirement for asserting a defense in a case at all. *See* 35 U.S.C. § 282. Since the district court invalidated Apotex USA's patents on summary judgment, and not at trial, Section 282's requirement concerning the identification of evidence "at trial" was simply inapplicable to the case at hand.

Apotex USA's argument also misses the mark because the purpose of Section 282 is to give a patent holder notice so that it may respond to evidence supporting a

validity challenge at trial and avoid trial by ambush. In the case at hand, there can be no doubt whatsoever that Apotex USA had full knowledge of the prior art upon which Merck relied for its challenge to the validity of Apotex USA's patents. In other words, this prior art was the very Merck process that Apotex USA accused of infringement and that Merck had practiced before Apotex USA claimed to have invented it. Apotex USA agreed that Merck had used the process previously, and the district court so concluded. Pet. App. B, 29a-30a, 34a. Moreover, to the extent that Apotex USA thought that it needed additional information concerning Merck's section 102(g) defense, Apotex could have filed a motion under rule 56(f) of the Federal Rules of Civil Procedure, but never did so. Finally, section 282 provides that "[i]n the absence of such [pretrial] notice proof of the said matters may not be made at the trial except on such terms as the court requires." Thus, even at trial, according to section 282, a trial court has the discretion to set the terms for proof of prior art defenses.

The primary issue decided by the district court and reviewed by the Federal Circuit was whether Merck acted so as to negate any suppression or concealment of its previous invention of the formulation process at issue. Merck set forth fully in its motion for summary judgment the "negating" acts and provided evidence of those acts. In response, Apotex USA never raised with the district court that it needed any additional information or that it believed that it did not receive any information that may have been useful in its response to Merck's summary judgment motion. Accordingly, section 282 was irrelevant to the district court's decision on summary judgment.

In any event, Apotex USA's contrived argument concerning section 282 does not raise an important question of federal law.

III. The Petitioner Takes Issue With the Lower Courts' Determination that No Genuine Issues of Material Fact Existed and the Application of Properly Stated Rules of Law, Neither of Which Warrants Exercise of This Court's Powers

Apotex USA's petition is loaded with accusations of deception and fraud on the patent system and the judiciary, in hopes of painting a picture of the judicial system running so grossly awry that the Supreme Court should issue a writ of certiorari. Merck obviously disagrees with Apotex USA's allegations, and, in accordance with Supreme Court Rule 15.2, to the extent not stated elsewhere in this opposition brief, Merck has outlined its disputes with Apotex USA's statements of the facts elsewhere in this brief.

No matter how Apotex USA attempts to spin the facts and the law, Apotex USA's argument that the Federal Circuit has sanctioned a departure from the accepted and usual course of judicial proceedings boils down to nothing more than what many petitioners undoubtedly present and what the Rules of the Supreme Court state are rarely the grounds for a writ of certiorari – a dispute with determinations about fact issues and the courts' application of properly stated rules of law.

A. The Federal Circuit Did Not Unacceptably Depart from the Usual Course of Judicial Proceedings

Apotex USA's argument that the district court's summary judgment conflicted with the Canadian court decision is blatantly false. *See* Pet. App. B, 34a-36a. The same issues were not before the Canadian court in that case, and the district court did not reach a decision contrary to that of the Canadian court.

Even if the district court's decision had conflicted with that of the Canadian court, Apotex USA has not shown how such a decision could justify this Court issuing a writ of certiorari. Contrary to Apotex USA's assertion, *Aetna Ins. Co. v. United Fruit Co.*, 304 U.S. 430 (1938) does not stand for the proposition that conflict between a district court decision and the decision of a foreign court is a reason for granting certiorari. *Aetna* is a case involving maritime law. This Court explained that, at the time of *Aetna*, U.S. jurisprudence looked to the jurisprudence of England for principles of maritime insurance law. *Id.* at 438. ("We recognize that established doctrines of English maritime law are to be accorded respect here...."). The Court granted certiorari in *Aetna* because it believed that a decision by the Second Circuit conflicted with the law applied by English courts in previous cases between completely different parties than those involved in the *Aetna* case. *Id.* at 434, 438. Ultimately, this Court affirmed the decision of the Second Circuit in *Aetna* because the English principles of maritime insurance law in question had never been adopted by an appellate court, had been doubted by eminent judges, and conflicted with established principles of maritime insurance law. *Id* at 438-39.

Apotex USA incorrectly argues that *Aetna* is legal authority for the argument that ***if*** factual findings differ (and they do not) or ***if*** legal conclusions differ (and they do not) between those in Merck's previous litigation in Canada and those in the present case, then certiorari would be proper. In *Aetna*, the courts of the U.S. had looked to the courts of England for specific maritime law principles. That is the reason why this Court granted certiorari in *Aetna* and, contrary to Apotex USA's argument, not because it saw the Supreme Court's duty as to ensure that all decisions of U.S. courts were consistent with those of foreign courts. This Court does not sit to square its decisions with those of courts

of other countries, and Apotex USA has cited no authority that certiorari would be justified to do so.

B. The Federal Circuit Did Not Ignore Evidence Justifying Certiorari

Apotex USA's petition is replete with misrepresentations as to the facts that underlie the Federal Circuit and district court opinions. Despite Apotex USA's continuous and desperate attempts to insinuate some sinister plot, the facts have now been reviewed four times and by two courts. It is undisputed that Merck was the first inventor of the process. And no reasoned argument can be made that Merck was suppressing or concealing the process at the time that Dr. Sherman allegedly invented it after the trial at the Canadian litigation. Therefore, the patents were rightfully adjudicated invalid. *See, e.g., Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985) (en banc), *appeal after remand*, 796 F.2d 456 (Fed. Cir. 1986).

1. The Courts Below Considered All of the Evidence

Apotex USA's argument that the district court and Federal Circuit assumed that the present case was one of concealment inferred from delay and not a case of "intentional concealment" is nothing more than a "red herring."

Apotex USA introduces its argument through *Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985). Contrary to Petitioner's discussion, while *Paulik* discusses some differences in various courts' treatment of different cases of suppression and concealment based upon the reasons for the suppression or concealment, *Paulik* does not hold that intentional concealment could not be negated by subsequent

acts. *Id.* at 1275-76. Instead, *Paulik* merely holds that an earlier inventor's resumed activity may negate a previous delay in reducing an invention to practice, allowing the first inventor to obtain a patent. *Id.* In this case, the courts applied the law to the facts and reached the particular result, that any suppression or concealment that Merck had committed had been negated by Merck's subsequent acts. Pet. App. 15a-16a, 33a-36a. Apotex USA simply disagrees with the decisions of the district court and Federal Circuit, and that disagreement did does not justify certiorari.

Apotex USA also rehashes its argument that Merck did not prove by clear and convincing evidence that the public had gained knowledge of the invention, Petition at p. 25, even though the law imposes no duty to prove any public awareness. *See* Section II.A., *supra*.

Along the way, Apotex USA makes a blatantly false allegation that Merck Frosst used "fake" ingredients in its videotape exhibit (narrated at the Canadian trial by Mr. McLeod) for "no reason," implying an intent on the part of Merck Frosst to deceive. This statement was blatantly false because, as Merck brought to the attention of the Federal Circuit, McLeod clearly explained in the Canadian trial that: 1) the materials were being shown only for purposes of illustrating the process in this visual, demonstrative video exhibit; and 2) representative materials were being used in place of actual ingredients for safety reasons:

> [Merck] chose not to use the active ingredients in this particular [video] production because when we took the lights into the production area, there was a concern about safety of stability and explosion with these particular active ingredients with the

> lights. So, in fact what you are actually looking at is a placebo at this stage.

Transcript of March 28, 1994 trial testimony of Brian McLeod in *Merck & Co., Inc. et al. v. Apotex, Inc.* in the Federal Court of Canada Trial Division at pp. 123-24, which was of record and included in the Joint Appendix to the appeal to the Federal Circuit at pp. A1067-68. Apotex USA omitted the cited material from the appendix to its petition.

In addition, Apotex USA's petition confusingly alleges that other acts by Merck were misleading and somehow created a genuine issue of material fact. Petition, at pp. 25-26. To do this, Apotex USA argues that the courts below overlooked the statements of Apotex USA's personnel and experts, despite the fact that those courts considered those statements. Pet. App. C, 41a-45a; Pet. App. A, 14a-17a.

2. The Courts Have Considered the Evidence Four Times

Again, emphasizing that the district court's decision did not conflict with the previous decision of the Canadian court and that even such a discrepancy would not amount to an unacceptable departure from the usual course of judicial proceedings, Merck asserts that Apotex USA's argument that the Federal Circuit ignored evidence is unfounded and inappropriate because the issue of suppression and concealment have been considered by the courts on four separate occasions before the present petition – by the district court on summary judgment; by the district court on petition for reconsideration; by the Federal Circuit on appeal; and by the Federal Circuit on petition for panel rehearing and rehearing en banc. Apotex USA lost at each and every step along the way to this Court, and it defies rational belief to

think that the courts ignored evidence on four separate occasions. The courts below did consider all of the evidence before them and reached the appropriate conclusion, albeit a conclusion that Apotex USA does not like. Apotex USA's allegations are outlandish and fall far short of the standard for certiorari.

C. Apotex USA's Argument About The Record as a Whole is Nothing More than Disagreement with Factual Findings

Apotex USA's argument about "the record as a whole" is a final cry of desperation based on nothing more than allegations of the district court's determination of the absence of genuine issues of material. Such a determination was purely within the province of the district court and was considered by the Federal Circuit on appeal. No basis for certiorari lies in "the record as a whole."

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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